
November 11, 2002

**VIA E-MAIL (fdadockets@oc.fda.gov)**
**VIA FACSIMILE (301-827-6870) and**
**U.S. FIRST CLASS MAIL**

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket Number 02N-0209**
**Response to Comments on First Amendment Issues**

Dear Sir or Madam:

The Indiana Medical Device Manufacturer's Council ("IMDMC") appreciates this opportunity to submit this response to comments on the Food and Drug Administration's (FDA) Request for Comment on First Amendment Issues. IMDMC is an Indiana-based trade association of about sixty medical technology manufacturers and others in allied fields.

We support FDA's commitment to ensure that its regulations and policies comply with the First Amendment, and we appreciate this opportunity to provide our input on this significant regulatory reform initiative. We realize the magnitude of FDA's undertaking, especially with regard to the issues at stake. As with all First Amendment issues, not only does regulation of the speech affect the rights of the "speaker," it also affects the rights of the intended audience to receive the speech.

Moreover, we understand and respect FDA's charge to protect the public's health and safety by ensuring that drugs and medical devices are safe and effective for human use. This mission, however, must be consistent with the First Amendment. On May 6, 2002, FDA published a request for comments on First Amendment issues in the *Federal Register*, the deadline for which was extended on July 10, 2002. FDA is now accepting responses to the comments that were submitted, and IMDMC is pleased to have this opportunity to express its agreement and disagreement with selected comments. We group our responses into six categories.

**Indiana Medical Device Manufacturers Council, Inc.**
P.O. Box 1385
Indianapolis, IN 46244
317-951-1388
Fax 317-974-1832
imdmcoffice@ameritech.net
www.imdmc.org

02N-0209

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## I. FDA Should Modify Its Present Stance Regarding Communications about Off-Label Uses of a Drug or Device.

FDA should modify its present stance regarding off-label communications because it is inconsistent with the First Amendment. As Schering-Plough explained: "Currently, FDA holds manufacturers of prescription products to a standard that requires any communication by those manufacturers about their products, even scientific and medical information, to be consistent with those products' FDA-approved labeling."[1] We concur with the company's conclusion that "instead of being focused on the approved labeling, FDA's restriction of commercial speech must be focused on the truth of the messages being disseminated in order to be constitutionally sound."[2] Clearly, "it goes without saying that even the currently approved package insert does not reveal everything that may be *true* about a drug product."[3] These principles are also true for medical devices.

How, then, should FDA determine the truth of a communication? Presently, FDA's method of determining whether something is "true" is to use a very high evidentiary standard. For example, to say or imply that a drug or device is safe and effective, in FDA's view the company must have two "adequate and well-controlled" clinical studies that support the determination that the product in question is in fact safe and effective for human use. In other words, according to FDA a company cannot claim or imply that its product is "safe and effective" without these supporting studies. Similarly, under its present regulatory stance, if FDA deems a claim regarding a drug or device to contain an implied claim that the product is safe and effective, FDA expects the company to have this same level of evidence.

Importantly, we agree with that approach for those claims. But that does not provide guidance on how other communications should be judged. Because *Central Hudson* obligates FDA to use the "least restrictive" means available to regulate commercial speech, FDA cannot make its evidentiary standard for product approval into the standard of truth for all statements. This is because the constitutional standard for regulation of commercial speech—truthful and non-misleading—for a specific off-label statement has to be judged by the facts and circumstances surrounding the particular communication. Factors such as (1) full disclosure of the data—favorable and unfavorable—and (2) the avoidance of implied claims through the use of disclaimers become very important to deciding whether a communication passes muster under the First Amendment.

As already noted, we recognize that a blanket statement that a product is safe and effective may be problematic if the safety and effectiveness of the product has not been proven under the same evidentiary standard as FDA applies in approving products. However, this is because such a statement may mislead consumers to believe that the evidence necessary to meet the approval standard exists. Thus, we believe that companies should not be allowed to make

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1 Schering-Plough, Comments to FDA, p. 3 (Sept. 13, 2002) (hereinafter "Schering-Plough").
2 *Id.*
3 *Id.* (emphasis added).

such blanket claims of safety and effectiveness unless the companies possess the evidence necessary to meet the approval standard.

On the other hand, manufacturers should be able to communicate data so long as they avoid making or implying a claim that a product is safe and effective. To do so, they should make a statement (that accompanies any communication regarding an off-label use) that FDA has not approved the product in question, and thus its safety and effectiveness has not been established. Moreover, to prevent its audience from being misled, the company should disclose enough relevant information about the off-label use, including positive and negative information, to achieve a fair balance. If it does those two things, the statements will be truthful and not misleading, especially if made to a sophisticated audience like physicians (see part II of this comment). Such statements thus should not be prohibited.

Comments advocating that FDA continue to equate the standard for product approval with the standard for all communications about the product were submitted by some members of Congress.[4] The congressmen addressed the topic of disclaimers, comparing the above-described disclaimers to the system of drug approval that existed before 1962. They asserted that a disclaimer indicating that "a claim had not been reviewed by FDA would provide no useful information to a physician about whether to prescribe the drug and would offer her patients no protection from unsafe or ineffective products, or from the harm that can flow from such products. . . ."[5] We respectfully disagree with this assertion. The crux of this disclaimer is that it prevents the communication from misleading physicians about the approval status of the product. Physicians, as the "learned intermediaries" between the product and the consumer, can then make an informed judgment about the appropriateness of allowing a patient access to the product for the patient's particular use. Truthful scientific information is a good thing.

Similarly, the congressmen criticize "a statement created by the manufacturer ostensibly providing adequate information for a consumer to assess the weight of the evidence supporting a claim."[6] In particular, the comments claim that companies will not conduct adequate tests and will not provide an objective presentation of the existing evidence.[7] We also disagree with these assertions. First, if FDA makes the rules of the road clear, the vast majority of companies will act responsibly and follow them. And second, for those that don't, FDA is perfectly able to enforce its rules. The risk that a few companies will not follow the law can hardly be a reason for prohibiting all speech. That is the essence of *Central Hudson*.

Because the First Amendment mandates that commercial speech be regulated in the least restrictive way possible, FDA should permit companies to communicate about off-label uses of their products if an effective disclaimer accompanies the communication, and if the company fully discloses the basis for its statements with fair balance.

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[4] Congress of the United States, Comments to FDA (Sept. 13, 2002) (hereinafter "Congress").
[5] Congress, *supra*, at 20-21.
[6] *Id.* at 20.
[7] *Id.* at 21.

## II. The Role of Physicians Calls for More Latitude in Regulating Speech.

Several comments noted the important role that physicians play as the audience for communications from manufacturers. As Johnson & Johnson explained:

> Physicians are also required by ethics and laws governing professional practice to assert their best medical judgment in prescribing the most appropriate products for a patient, based on the condition, medical history, and circumstances presented by that patient. The physician, as a "learned intermediary," is the actor who possesses the greatest knowledge of the particular patient's needs, the medical and clinical knowledge of the patient's disease state, and the medical and clinical knowledge that will lead to the prescription of appropriate products to meet the patient's needs.[8]

We would like to emphasize the need for a greater information flow to that audience, and the legal basis for that latitude.

### A. Sound Policy Reasons Exist for a Freer Flow of Speech to Physicians.

While there are many advantages to moderating the impediments to sharing information with health care providers, we have distilled those reasons down to five important ones.

First, doctors and other health care providers have moral and licensing obligations to exercise their professional judgment to provide the highest quality care. To provide that care, doctors need the latest information on the safety, effectiveness, and cost/benefit for all uses of devices and drugs, including those uses that are unapproved. Using governmental regulation to limit the flow of information from companies to doctors runs counter to the moral and legal obligations that society imposes on doctors to exercise their professional judgment in providing care. From a basic public health standpoint, physicians simply need the best and most recent information to provide the highest quality care at the lowest cost. Conversely, the responsibility for those drug and device selection decisions rests with the care provider, who cannot properly exercise that professional charge without full information access.

Second, like other sciences, medicine advances when physicians and other scientists piece together existing information to develop new theories that can be tested, thus producing new information. This system works best when information flows freely. A piece of information in the hands of a device or pharmaceutical company could be just the information needed by a researcher across the country struggling to develop a cure for a different disease. And, while some would challenge the objectivity of device or pharmaceutical companies in presenting information, few would dispute that companies know a great deal about the products they make. For pharmaceutical companies, this is true if for no other reason than because the

[8] Johnson & Johnson, Comments to FDA, p. 7 (Sept. 13, 2002) (hereinafter "Johnson & Johnson").

company is required by regulations to provide annual reports to FDA for all marketed products, which includes a summary of all pertinent studies and publications relating to each drug.[9]

Third, all truthful information on safety, effectiveness, and cost/benefit has value that can be determined and weighed by a sophisticated audience. Health care decisions must be made every day, and these ought to be based on the best available information whether or not that information is supported by "substantial evidence." Given the rate of technological change, the need for information dissemination is immediate. Society cannot afford for FDA to act as a gatekeeper for information regarding products that FDA already has approved as safe and efficacious.

Fourth, information sharing helps reduce inappropriate variation in health care. It is well known that medical treatments vary widely, and often without discernible cause. Sharing information allows health care providers to target process defects and move toward the best, standardized practices. At the same time, information can allow physicians to exercise intelligent judgments about when variation is appropriate for individual patients. In short, supplying health care providers with fuller information than what is contained in the package insert allows them to tailor treatments to the idiosyncrasies of both individual patients and specific populations. Limitations on information access confound this process.

Fifth, the unrestricted dissemination of credible information such as treatment protocols and journal articles to health care providers by companies streamlines the education process. It is not feasible for doctors and other health care providers to read all journal articles by individually subscribing. There are more than 30,000 medical journals in the world for doctors to read, producing millions of pages each year.[10] Information, to be useful to physicians with little time for reading, needs to be efficiently presented in a convenient vehicle. Companies can provide this service by collecting and presenting materials to physicians in a way that allows the doctors to gain a quicker understanding of the important issues, and that also discloses to physicians the regulatory status of the uses described in the article. A patient should not be denied the latest care just because her doctor does not happen to subscribe to the journal that published a breakthrough article. Patients deserve the opportunity to benefit from new observations, and such opportunity should not be dependent on "happenstance" informational findings.

### B. A Sound Basis in Law Exists for Judging Such Communications Differently from Communications to Patients.

Courts have repeatedly held that compliance with section 502(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA")[11] should be judged by the meaning of the words to the

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[9] 21 C.F.R. § 314.81 (2002).

[10] Telephone Interview with National Library of Medicine, Bethesda, Maryland (Oct. 18, 1995).

[11] Section 502(a) addresses misbranded drugs and devices.

audience to which the labeling is directed.[12] In line with that test, courts have interpreted section 502(a) as imposing a higher burden for substantiation when the audience is unsophisticated.[13]

FDA has apparently embraced that interpretation of section 502(a) because the agency has in several situations used section 502(a) as a basis for requiring that labeling be tailored to the level of the particular audience. A classic example is the agency's requirement of a patient package insert that is tailored to the sophistication of patients, in contrast to the professional labeling tailored to the level of health care providers.[14] For example, the agency currently requires patient labeling for oral contraceptives and estrogen products.[15] When the agency earlier sought to impose a broad requirement of a patient package insert tailored to the reading comprehension of patients, the agency explained that professional labeling could not fulfill the needs of most patients for understandable information about prescription drugs because that labeling is too technical for most patients to understand.[16] The agency used section 502(a) to justify an affirmative requirement of special labeling tailored to the patient level.[17] Thus, FDA apparently has already concluded that section 502(a) requires that drug and device labeling be tailored to the level of the audience.

By force of logic, the converse of FDA's conclusion that section 502(a) requires special labeling for unsophisticated audiences must also be true. That is, when an audience is particularly sophisticated, FDA needs to take that fact into account when judging the appropriateness of labeling directed at that audience. Part of that appropriateness is the level of substantiation for the labeling and the disclosure of the methods of research. Thus, section 502(a), *by FDA's own interpretation and those of the courts*, compels the agency to adopt different substantiation requirements for labeling depending on the sophistication of the audience.

From a First Amendment point of view, while the federal government has a substantial interest in the flow of information about devices and drugs, FDA's current approach to regulating post-approval information fails the *Central Hudson* test because, among other things, it is more extensive than necessary to serve the government's interest. FDA's current overly-broad regulatory approach censors the flow to *all* audiences of post-approval information not meeting the artificially high standard for approving new products. FDA must therefore address the propriety of applying the approval standard to information provided to highly trained physicians. We think more latitude is required.

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[12] V.E. Irons, Inc. v. United States, 244 F.2d 34 (1st Cir. 1957), *cert. denied*, 354 U.S. 923 (1957); United States v. 23, More or Less, Articles, 192 F.2d 308, (2d Cir. 1951); United States v. Vrilium Prods. Co., 1938-1964 F.D.L.I. Jud. Rec. 944 (N.D. Ill. 1950), *aff'd*, 185 F.2d 3 (7th Cir. 1950), *cert. denied*, 340 U.S. 947 (1951).

[13] *E.g.*, United States v. Hoxsey Cancer Clinic, 198 F.2d 273 (5th Cir. 1952), *cert. denied*, 344 U.S. 928 (1953); United States v. Articles of Drug, 263 F. Supp. 212 (D. Neb. 1967); United States v. Vitamin Indus., Inc., 130 F. Supp. 755 (D. Neb. 1955); United States v. Ten Cartons, More or Less, 1938-64 F.D.L.I. Jud. Rec. 1519 (1957).

[14] Prescription Drug Product Labeling Medication Guide Requirements, 60 Fed. Reg. 44,182 (Aug. 24, 1995).

[15] 21 C.F.R. §§ 310.501, 310.515 (2002).

[16] Prescription Drug Products; Patent Package Insert Requirements, 45 Fed. Reg. 60,754 (Sept. 12, 1980), cmt. 7.

[17] *Id.* at cmt. 1.

## III. FDA Should Revise Existing Regulations that Indirectly and Unconstitutionally Regulate Commercial Speech.

IMDMC is very concerned about the manner in which FDA uses some of its existing regulations to indirectly regulate commercial speech. In particular, we agree with AdvaMed's comments on FDA's "intended use" regulation in 21 C.F.R. § 801.4:

> As drafted, the so-called "catch 22" provision potentially conflicts with a manufacturer's ability to freely disseminate information about off-label uses or unapproved product information contained in the peer-reviewed journal article or abstract—effectively requiring the manufacturer to submit a marketing application to FDA for that off-label or unapproved product upon dissemination of this type of information. This regulation should be revised to allow a manufacturer to disseminate truthful non-misleading information without imposing restrictions on speech.[18]

We agree with this statement and would like to elaborate on our concerns relating to section 801.4. Section 801.4 provides that the "intended uses" of a medical device:

> [R]efer to the objective intent of the persons legally responsible for the labeling of devices.... This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

The regulation then goes on to require that for these uses, the manufacturer must supply adequate labeling. But a manufacturer cannot revise the labeling without getting it approved. Through warning letters, FDA has used this section to regulate manufacturers' websites, marketing brochures, journal advertisements, and other promotional articles.[19] In these letters, FDA warns the manufacturers to correct these violations. Thus, through section 801.4, FDA makes it illegal to communicate about an off-label use.

As outlined in the prior section, we believe FDA should permit communications about off-label uses that are not false or misleading. To permit that sort of communication, we believe FDA needs to amend section 801.4 to not require labeling for off-label uses.

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[18] Advanced Medical Technology Association, Comments to FDA, pp. 10-11 (Sept. 13, 2002) (hereinafter "AdvaMed").

[19] *E.g.*, Letter from HHS, FDA, CDRH, to Peter Klein, Chief Executive Officer, Diomed Incorporated (Nov. 5, 2001) (on file with FDA); Letter from HHS, FDA, CDRH, to Fred Hassan, Chief Executive Officer, Pharmacia & Upjohn (Sept. 21, 2001) (on file with FDA); Letter from HHS, FDA, CDRH, to Kenneth Anstey, President and CEO, Oratec Interventions, Incorporated (Aug. 17, 2001) (on file with FDA).

FDA cannot use this regulation as an end-run around the requirements of the First Amendment.[20] As the comments of PhRMA explained: "If the agency cannot regulate speech directly under the full *Central Hudson* test, it may not regulate it indirectly by using the speech as per se evidence of unlawful conduct."[21] As applied here, communication regarding off-label use falls under the rubric of *Central Hudson* because it concerns truthful speech and is not misleading. Under *Central Hudson*, FDA's use of section 801.4 is not the least restrictive means for FDA to advance the agency's interest.

Indeed, as an alternative to the current approach, if FDA is concerned about off-label use of a device, it can require manufacturers to put a warning on the device stating the uses for which FDA has approved the device and specifically disclaiming that other uses have not been approved. Warnings adequately advise consumers of the risks associated with the use of a medical device, and they do not infringe First Amendment rights.

In sum, *Central Hudson* does not permit FDA to directly prohibit truthful commercial speech regarding off-label use; nor can it do so indirectly.

## IV. FDA Should Recognize that Incentives Already Exist that Compel Manufacturers to Seek FDA Approval and to Communicate Only Truthful and Non-Misleading Information about Off-Label Uses of Their Product.

One reason FDA asserts for the prohibition of off-label information is the desire to create an incentive for companies to seek FDA approval. Many comments disagreed, and we would like to add our experience to the discussion. Our experience demonstrates that there already are incentives for a company to seek FDA approval, and there are also incentives to communicate only truthful and non-misleading information relating to off-label uses of a product.

### A. The Potential Loss of a Preemption Defense Influences Companies to Seek FDA Approval.

Obviously marketing reasons influence companies to seek FDA approval—it is a seal of approval that is widely respected in the marketplace. Moreover, there is a marketing benefit to bringing a use on label so that it gets attention from end users. But more than that, there are legal reasons to seek FDA approval.

The potential loss of the defense of preemption in a product liability action influences companies to seek FDA approval. In particular, the 1976 Medical Device Amendments contain an express provision that preempts certain state requirements respecting a medical device.

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[20] *E.g.*, Food Lion, Inc. v. Capital Cities/ABC, Inc., 194 F.3d 505 (4th Cir. 1999) (disallowing plaintiff to recover damages for reputation-related claims that satisfied state law requirements but that did not satisfy the higher standards of the First Amendment).

[21] Pharmaceutical Research and Manufacturers of America, Comments to FDA, p. 23 (Sept. 13, 2002) (hereinafter "PhRMA").

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[22]

FDA regulations interpret section 360k as preempting *any* requirement, "whether established by statute, ordinance, regulation, or court decision."[23]

In addition, courts have interpreted section 360k as preempting state express warranty claims that are based upon "FDA-mandated labeling, packaging, or advertising."[24] In general, a state express warranty claim holds a seller liable for making an affirmation of fact or a promise that induces a buyer to purchase a product, but which the seller ultimately does not fulfill.[25] However, if a manufacturer-defendant fails to comply with FDA regulations governing medical devices, the defendant can lose its preemption defense and be sued on the state claim.[26]

The preemption defense thus provides an incentive for manufacturers to seek FDA approval and promote only on-label uses of their device. Because manufacturers realize that communications about an unapproved use for a product may lead them into a product liability action for which they have no preemption defense, they tend to seek FDA approval and limit their communications to on-label uses.

### B. Legal Liability Influences Companies to Communicate Only Truthful and Non-Misleading Information Regarding Off-Label Uses of Their Product.

Quite apart from regulatory requirements, the marketplace itself and the civil liability system ensure honesty. The increased competition in the drug and device industries acts as a self-policing mechanism. History suggests that device and drug companies closely scrutinize each other's comparative claims. Thus, any false or misleading information would undoubtedly be brought to the attention of the market by a competitor. Companies taking liberties with the

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[22] 21 U.S.C. § 360k(a) (2002).

[23] 21 C.F.R. § 808.1(b) (2002).

[24] Duvall v. Bristol-Myers-Squibb Co., 103 F.3d 324, 332 (4th Cir. 1996); *see also*, Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090, 1100 (6th Cir. 1997). Although the Supreme Court has held that section 360k does not preempt certain state law claims, federal courts, as explained, have subsequently affirmed that state express warranty claims are not within the scope of the Court's holding. Medtronic v. Lohr, 518 U.S. 470 (1996).

[25] *E.g.*, Friedman v. Medtronic, 345 N.Y.S.2d 637 (N.Y. Sup. Ct. 1973).

[26] *See* Martin, 105 F.3d at 1101.

truth would lose their reputation in the marketplace, which is perhaps the most devastating penalty of all.[27]

Moreover, drug and device companies also would have legal redress to bring suit against each other for false advertising under section 43 of the Lanham Act.[28] And device and drug purchasers could sue manufacturers that make false claims to induce a sale.[29] All of these mechanisms provide significant incentives for device and drug companies to act with integrity as they make claims.

Many of the comments touched on product liability. We would like to further elaborate on the significance of product liability as relating to speech. In particular, we strongly believe that product liability creates a strong disincentive to communicating false or misleading information about off-label uses of products.

A manufacturer can create liability for itself by overzealously or irresponsibly marketing its product.[30] Indeed, a manufacturer may be liable if it "overpromotes" and "underwarns" a physician with regard to a drug or device, even if a physician denies relying on the promotional literature at issue.[31]

Thus, to avoid potentially costly product liability actions, manufacturers must not communicate an inaccurate or unbalanced view of the state of information that exists with respect to a product. Indeed, in some cases, the risk of losing this defense may even cause a manufacturer to communicate only about approved uses for a product (and to do so in a truthful and balanced manner).

## V. FDA Should Modify Its Stance on Scientific and Technical Information so that It Conforms with the First Amendment.

### A. ~~FDA Should Recognize that Peer-Reviewed Scientific and Technical~~ Information Mandates More Protection than Commercial Speech and May Be Suppressed Only upon the Most Compelling of Circumstances.

Many comments expressed deep concern regarding FDA's present regulatory stance on the dissemination of scientific and technical information. We share this same concern. In

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[27] *See* Comments of the Staffs of the Bureau of Economics and Consumer Protection of the Federal Trade Commission before the Department of Health and Human Services Food and Drug Administration in the matter of Pharmaceutical Marketing and Information Exchange in Managed Care Environments; Public Hearings at 11 [Docket No. 95N-0228] (Jan. 16, 1996).

[28] 15 U.S.C. § 1051 *et seq.* (2002).

[29] *E.g.*, Allen v. G.D. Searle & Co., 708 F. Supp. 1142 (D. Or. 1989); Grinnell v. Charles Pfizer & Co., 79 Cal. Rptr. 369 (App. 1969); Toole v. Richardson-Merrell, Inc., 60 Cal. Rptr. 398 (App. 1967); Tetuan v. A.H. Robins, 738 P.2d 1210 (Kan. 1987).

[30] A manufacturer might also expose itself to state law claims for negligent misrepresentation, if a purchaser relies on the representations or "overpromotions." *E.g.*, Fane v. Zimmer, 927 F.2d. 124, 130 (2d Cir. 1991).

[31] Holley v. Burroughs Wellcome Co., 348 S.E.2d 772 (N.C. Sup. 1986); *see also* Stevens v. Parke Davis & Co., 507 P.2d 653, 661-62 (Cal. 1973).

particular, we believe that FDA should consider the nature of this information and its place within First Amendment jurisprudence. We would like to suggest to FDA that this type of speech is *not* commercial speech. As PhRMA's comments explained:

> [W]hen researchers affiliated with a company publish study findings in a medical or scientific journal, the publication should not be considered commercial. Other examples of at least presumptively non-commercial speech include medical and scientific information provided in response to unsolicited requests for the information, the exchange of scientific data at scientific meetings, and non-promotional press releases announcing research findings.[32]

We agree that the above-described speech is not proposing a commercial transaction. Moreover, this type of speech is at the heart of First Amendment protection. Free dissemination of scientific and technical information often has the potential to directly advance the quality of medical care. Indeed, it is difficult to underestimate the importance of a free and open dialogue among the producers of medical technology, those who apply that technology, and those who need that technology. This is the type of speech that must be protected at all costs, and we are convinced that it is imperative that FDA reconsider its stance on scientific and technical speech.

We both agree and disagree with the comments of the Public Citizen Health Research Group ("Public Citizen"), which argued that "[g]overnment must play an active role in proctoring the information drug and medical device manufacturers provide to physicians and patients because the incentives for the manufacturers to distort the 'truth' by providing the public a misleading, one-sided presentation of the scientific evidence, are enormous."[33] While we disagree with their assertion of the incentives to distort the truth (see part IV above), we agree that FDA has a role to proctor the information. As the industry regulator, FDA does and should continue to serve the function of policing and enforcing the rules requiring truthful information. But the proctoring role does not include censoring truthful information, and that is what the First Amendment prohibits FDA from doing.

### B. FDA Should Not Regulate the Dissemination of Peer-Reviewed Materials Based upon Who Is Communicating the Information.

We believe FDA's present limitations on *who* may disseminate peer-reviewed materials are unconstitutional. As we understand it, FDA prefers that sales representatives not be allowed to disseminate information pertaining to off-label uses. We question the constitutionality of such a distinction in light of the Supreme Court's expressed reservations about regulations that use the identity of the speaker to regulate speech. For example, the Court has explained that "[t]he inherent worth of the speech in terms of its capacity for informing the public does not depend

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[32] PhRMA, *supra*, at 5.

[33] Public Citizen Health Research Group, Comments to FDA, p. 3 (Sept. 13, 2002) (hereinafter "Public Citizen").

upon the identity of its source, whether corporation, association, union, or individual."[34] Thus, "[i]n the realm of protected speech, the legislature is constitutionally disqualified from dictating the subjects about which persons may speak and the speakers who may address a public issue."[35]

Scientific and technical information about off-label uses is protected speech, regardless of who distributes it. Thus, FDA's distinction that separates sales representatives from other company personnel simply does not pass constitutional muster. As explained above, because this speech is constitutionally protected, FDA cannot dictate which speakers may disseminate the information. Moreover, as a practical matter, we note that in many organizations, no clear line exists between "sales representatives" and "headquarters personnel." Thus, such a distinction is overly vague and unenforceable, as it would not be possible to tell who could engage in speech and who could not.

## VI. FDA Should Develop Clear Policies that Encourage the Free Flow of Information.

As a general matter, we encourage FDA to assess its stance on commercial speech in light of its mission, which is not only to protect public health, but also "to *promote* the public health by . . . taking appropriate action on the marketing of regulated products in a timely manner."[36] We believe, as do many other individuals and organizations commenting, that FDA may better fulfill this charge by promoting the free flow of truthful and non-misleading information among the medical community.

Unfortunately, ambiguous FDA regulations and policies on commercial speech may unintentionally help unethical companies thrive. When FDA adopts rules that prohibit otherwise constitutional conduct, ethical companies, out of respect for the agency and concern for their reputation, abide by the agency's regulation. In our experience, ethical companies almost always make a conscious decision to abide by the agency's decision and to not exploit an ambiguity or potential unconstitutionality. Other companies, however, do not hold themselves to such standards. For whatever reason, whether they are unethical or simply desperate to survive in a competitive market, some companies seize upon ambiguity and exploit any possible advantage.

This harms both FDA and the public that FDA is charged to protect. In our experience, when this occurs, FDA may not bring an enforcement action because it recognizes the ambiguity. This has the effect of helping unethical or "fly by night" companies to flourish, which clearly does not benefit the public. And it simultaneously disadvantages ethical companies, which in turn stunts the development of quality products that benefit the medical community and public.

Clarification of FDA policies will help to avoid this problem. In particular, if FDA develops unambiguous policies and regulations, companies that may have formerly been able to exploit FDA's policies will be forced to adhere to FDA policy. Any violations will be clear, and FDA will therefore be in a better position to bring—and win—an enforcement action. Clearly, unambiguous and constitutional regulations and policies will have a direct benefit to the public.

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[34] First Nat'l Bank of Boston v. Bellotti, 435 U.S. 765, 777 (1978).
[35] *Id.* at 784-785.
[36] 21 U.S.C. § 393(b) (2002) (emphasis added).

* * * * *

**Conclusion**

Over the last 30 years, sources of drug and device-related information have shifted dramatically. Formerly, medical schools were the driving force behind all medical research, including research related to pharmaceuticals and devices. In recent years, however, partly because of the escalating costs of such research, the device and pharmaceutical industries themselves have driven the research related to their products and have sponsored research at a wide variety of institutions. In addition, industry is now the source of a wide range of original research and employs highly skilled professional staff with scientific credentials on par with many academic settings. Thus, the device and pharmaceutical industries have become a principal source and repository of device and pharmaceutical information.

The irony of FDA's current regulatory approach toward device and pharmaceutical information is that those individuals with arguably the *most* information can say the *least*, and that those responsible for caring for patients are treated as unsophisticated consumers.

Equally troubling is the fact that FDA's policy encourages misinformation to go unchallenged. For a variety of reasons, FDA does not have jurisdiction over those outside of the chain of distribution for devices and pharmaceuticals. As a result, given the fast-changing means by which information can be disseminated, there are significant amounts of largely unregulated device and pharmaceutical information disseminated each day through vehicles such as the Internet. Much of it, by any standard, is of questionable quality. But device and pharmaceutical companies cannot rebut much of the misinformation that enters the marketplace from unregulated sources unless they have information that meets the approval standard test or unless first specifically asked.

As the FDA proceeds with its review, it is imperative that the agency keep in mind the extraordinary value of the information its regulations currently impede. We appreciate this opportunity to add our concerns to the comments that were previously submitted in response to FDA's request and applaud FDA's efforts to ensure that its regulations, policies, and procedures are consistent with the First Amendment.

Respectfully submitted,

Bradley Merrill Thompson
Secretary and General Counsel
Indiana Medical Device Manufacturers Council